Individual Safety Report

3537498-7-00-01

Watch

CDER

Approved by FDA on 10/20/93

FDA MEDICAL PRODUCTS REPORTING PROGRAM

Triage unit sequence # 126713

CDER

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1&2

A. Patient Information

1. Patient Indentifier	2. DOB: [redacted] AGE: 57 yrs	3. Sex	4. Weight
[redacted]		MALE	97.1 kg

B. Adverse Event or Product Problem

1. [X]Adverse Event [ ]Product problem

2. Outcomes attributed to adverse event
- [ ] death:
- [X] life-threatening
- [X] Hospitalization initial or prolonged
- [ ] disability
- [ ] congenital anomaly
- [X] required intervention to prevent impairment/damage
- [ ] other

3. Date of event: 03/30/00

4. Date of this report: 07/29/00

5. Describe event or problem
CONFUSION . hepatotoxicity

6. Relevant test/laboratory data, including dates
See attached

7. Other relevant History, including preexisting medical conditions
see attached

C. Suspect Medication(s)

1. Name
#1 : ACETAMINOPHEN

2. Dose, frequency & route used
#1:

3. Therapy dates
#1 :

4. Diagnosis for use(indication)
#1:

5. Event abated after use stopped or dose reduced?
#1: [N/A]

6. Lot # (if known)
#1:

7. Exp. date
#1:

8. Event reappeared after reintroduction
#1: [ ]

9. (Not applicable to adverse drug event reports)

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10. Concomitant medical products/therapy dates(exclude treatment)

D. Suspect Medical Devices

Note: Please use the actual MedWatch form if the event involves a suspected device as well as a suspect drug

E. Reporter

1. Name, address & phone #: [redacted]
5 th and Roosevelt RD Hines VA Medical center
HInes. ILLINOIS 60141 750-5417

2. Health professional? [YES]

3. Occupation: CLINICAL PHARM

4. Reported to Mfr: [NO]

5. If you don't want your identity disclosed to the Manufacturer, place an "X" in the box.[X]

Mail to: MedWatch
5600 Fishers Lane
Rockville, MD 20852-9787

or FAX to:
1-800-FDA-0178

FDA Form 3500

Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.

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THE FDA MEDICAL PRODUCTS REPORTING PROGRAM
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Hines VA Hospital: Patient Identifier [redacted] on 3/30/00

Patient was admitted for lethargy and confusion and inability to perform usual activities x 3 days. Patient had been taking a lots of pain medications for severe DJD with hx L1 compression fx. Pain medications were Oxycodone 5mg with acetaminophen 325mg 2 tablets q6h, Fentanyl patch, Gabapentin and Naproxen for long term. And tramadol 50 mg q6h were added 3 weeks before admission. Also Patient has been taking Tylenol PM as needed per wife and patient had questionable hx of acetaminophen excess with Tylenol PM 4 days prior admission. patient was found with elevated transminases with acute hepatic injury and acute renal failure on admission (3/30/00) Patient was treated with activated charcoal x 1 and mucomyst x 17 doses for acetaminophen toxicity. Elevated transminases (ALT 5755, AST 6175) on 3/30/00 were slowly resolved and patient's mental status has been improved. ALT 70 & AST 33 on 4/11/00 and renal function is back to normal (Cr. 1.0).

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